Proposed Decision Memo for Wrong Surgery Performed on a Patient (CAG-00401N) COMMENT

Proposed Decision Memo

TO:	Administrative File: CAG-00401N
FROM:	Steve Phurrough, MD, MPA Director, Coverage and Analysis Group Marcel E. Salive, MD, MPH Director, Division of Medical and Surgical Services Madeline Ulrich, MD, MS Lead Medical Officer Sarah McClain, MHS Lead Analyst
SUBJECT:	Proposed Coverage Decision Memorandum for Wrong Surgical or Other Invasive Procedure Performed on a Patient
DATE:	December 2, 2008

I. Proposed Decision

The Centers for Medicare and Medicaid Services (CMS) proposes that when a Medicare beneficiary requires a particular surgical or other invasive procedure to treat a particular medical condition and the practitioner erroneously performs a different procedure, Medicare will not cover that procedure because it is not a reasonable and necessary treatment for the Medicare beneficiary's particular medical condition.

A surgical or other invasive procedure is considered to be the wrong procedure if it is not consistent with the correctly documented informed consent for that patient. It excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. The event is not intended to capture changes in the plan upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation; or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae).

Surgical and other invasive procedures are defined as operative procedures in which skin or mucous membranes and connective tissue are incised or an instrument is introduced through a natural body orifice. Invasive procedures include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include all procedures described by the codes in the surgery section of the Current Procedural Terminology (CPT) and other invasive procedures such as percutaneous transluminal angioplasty and cardiac catheterization. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include use of instruments such as otoscopes for examinations or very minor procedures such as drawing blood.

We are requesting public comments on this proposed determination pursuant to section 1862(1) of the Social Security Act. After considering the public comments, we will make a final determination and issue a final decision memorandum.

II. Background

Rising concern about the monetary costs and physical harms to patients from medical errors led to a number of publications about the problem in the late 1990s. The Institute of Medicine report, *To Err Is Human*[1], published in 1999, called attention to statistics from the American Hospital Association that indicated that the death rate from medical errors could range from 44,000 to 98,000 per year with costs estimated in the tens of billions of dollars. It became clear that there needed to be a method for accurately identifying and reporting errors, tracking their consequences and establishing processes to prevent their occurrence.

In 2002, the National Quality Forum (NQF) published *Serious Reportable Events in Healthcare: A Consensus Report*[2], which listed 27 adverse events that were "serious, largely preventable and of concern to both the public and health care providers." These events and subsequent revisions to the list became known as "never events." This concept and need for the proposed reporting led to NQF's "Consensus Standards Maintenance Committee on Serious Reportable Events," which maintains and updates the list which currently contains 28 items. Among surgical events on the list is "Wrong surgical procedure performed on a patient."

Medicare beneficiaries are not immune from these events. They experience serious injury and/or death if wrong surgeries are performed and require additional healthcare in order to correct adverse outcomes resulting from these errors. In order to address and reduce the occurrence of these surgeries CMS internally generated a request for an NCD to determine whether performing the wrong surgery on a patient, i.e. a surgical procedure other than the intended procedure, is reasonable and necessary under the Medicare program.
Coverage of and payment for services related to a noncovered surgery or procedure are addressed in the Medicare Benefit Policy Manual and would be applicable to wrong surgical or other invasive procedure performed on a patient after this proposal is finalized. These policies are included in Chapter 1, section 10; Chapter 1, section 120; and Chapter 16, section 180.

III. History of Medicare Coverage

Medicare has not previously developed NCDs that address coverage for wrong surgical or other invasive procedures performed on a patient.

Benefit Category Determination

For an item or service to be covered by the Medicare program, it must meet one of the statutorily defined benefit categories in the Social Security Act. Surgeries performed on a patient, at a minimum, falls under the benefit categories set forth in section 1861(b) (inpatient hospital services), a part A benefit under 1812(a)(1) and 1861(s)(1) (physicians services), a part B benefit.
This may not be an exhaustive list of all applicable Medicare benefit categories for these services.

IV. Timeline of Recent Activities

July 31, 2008	CMS opened an internally generated NCD addressing coverage for wrong surgery performed on patients. Initial 30-day public comment period began.
August 30, 2008	Initial 30-day public comment period closed.
December 2, 2008	Proposed decision memorandum posted; 30-day public comment period begins.

V. Assessment

Assessment Questions

- What is the definition of “wrong surgical procedure performed on a patient?”
- What is the scope of surgical procedures that are included in the event “wrong surgical procedure performed on a patient?”
- Is a wrong surgical procedure performed on a patient ever reasonable and necessary?

In general, we determine something to be reasonable and necessary if we find evidence that demonstrates that an item or service improves health outcomes. However, in this instance, an evidentiary review is unnecessary to determine that performing a wrong surgical or invasive procedure on a patient will not improve health outcomes and harms the patient. We will discuss below the consensus in the healthcare community on the lack of benefit of these procedures.

1. Evidence

CMS examined various reports and reviews that address performing the wrong surgical procedure on a patient. Many of the articles written about surgical errors group errors relating to erroneous site, wrong procedure performed and wrong patient into “wrong site surgery.” Estimating rates of erroneous surgery is limited because of a lack of reporting requirements. A 2006 study by Kwaan et al., reviewing 10 years of data from a large malpractice insurer encompassing 2.8 million procedures, reported an incidence of 1 in 112994 operations of non-spine wrong site operations (Kwaan et al. 2006). This study is widely quoted and cited in a discussion of the study in a 2007 article in the Annals of Surgery which raises the point that the incidence of a “devastating outcome of a wrong site surgery” is not known, but might be expected to occur “once each year in a 300-bed hospital” and “surgeons who work on symmetrical structures may have a 1 in 4 chance to be involved in a wrong-site error during their careers” (Clarke et al. 2007).
Although accurate estimates of the numbers of erroneous surgeries are not available because of lack of uniform reporting an AHRQ supported study published in the April 2006 issue of Archives of Surgery reported that the three types of “wrong site surgeries” are extremely rare and major injury from them is even rarer. This study concluded that two-thirds of the errors studied could have been prevented by existing site verification protocols. However, many of the protocols “involve considerable complexity without clear added benefit” (Clarke et al. 2006). The 2009 safety goals (see below) are a step toward solving this problem. A number of specialty groups including orthopedic surgery and interventional radiology and states including Florida, Oregon and Minnesota, among others, are putting special emphasis on tracking, reporting and preventing these surgical errors.

2. Professional Society Position Statements

NQF has defined each of the serious reportable events on its current list. For this event, NQF has the following definition:

> Any surgical procedure performed on a patient that is not consistent with the correctly documented informed consent for that patient. It excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. The event is not intended to capture changes in the plan upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation; or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae) (NQF 2006 Update).

In developing its list of serious reportable events, NQF defined the scope of surgical procedures that it recommended for inclusion in the reportable adverse surgical events:

> Surgery is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue are incised or an instrument is introduced through a natural body orifice. Surgeries include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include use of instruments such as otoscopes for examinations or procedures such as drawing blood (NQF 2006 Update).

NQF also recommended that organizations further refine this as needed for its particular needs.

In July 2003, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) approved the "Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery™,"[3] which was designed to help prevent such errors. The document's introduction states: "Wrong site, wrong procedure, wrong person surgery can be prevented. This universal protocol is intended to achieve that goal. It is based on the consensus of experts from the relevant clinical specialties and professional disciplines and is endorsed by more than 40 professional medical associations and organizations." The principal components of the Universal Protocol include:

- A pre-procedure verification process
- Marking of the procedure site.
- A "time out" immediately before the start of the procedure.
- Adaptation of these steps to non-operating room settings for procedures performed in other places, such as at bedside.

The protocol became effective for all JCAHO accredited hospitals, ambulatory care and office-based surgery facilities on July 1, 2004. At the Wrong Site Surgery Summit in 2007 co-convened by JCAHO, the universal protocol was revised to include new performance elements and changes to improve consistency which will become effective January 1, 2009. Summit participants included surgeons, physicians, nurses, risk managers and partner organizations whose purpose was to clarify and improve the protocol to enable better compliance. The changes are also part of JCAHO's 2009 National Patient Safety Goals. Also new for 2009 are specific Office-Based Surgery National Patient Safety Goals. The changes may be viewed on the JCAHO website. [4,5,6]

3. Public Comments

CMS received four public comments during the initial 30-day public comment period. Each comment collectively addresses the three NCAs examining surgical event errors. In addition to this analysis they address CAG-00402N and CAG-00403N. Due to the limited number of comments received and the brevity of each comment, separate summaries of each are provided below.

American Hospital Association (AHA)

The AHA identifies three key questions CMS must explore in developing NCDs addressing surgical event errors: 1) how are the events defined; 2) how will accountability for the event be assigned; and 3) what costs or services should not be covered? The AHA asserts that CMS "must thoughtfully and carefully define the events it includes under the national coverage determination." Their comments reference principles the AHA has adopted to communicate to hospitals when to expect nonpayment from patients or insurers for care related to serious, preventable events. These principles include "1) the error or event must be preventable; 2) the error or event must be within the control of the hospital; 3) the error or event must be the result of a mistake made in the hospital; 4) the error or event must result in

significant harm; and 5) the error or event must be clearly and precisely defined in advance."
The AHA expresses concern regarding wrong-site surgeries. They contend that CMS must develop strategies to address circumstances in which a possible wrong-site surgery was begun, but was corrected before harm was incurred. The AHA asserts that CMS must set clear boundaries of what is and is not defined as a wrong-site surgery.
The AHA notes that "hospitals have begun to report more nuanced instances" of errors and contends that CMS' coverage decision should not result in limiting the reporting of such events. The AHA stresses the importance of reporting these "more nuanced" errors for advancing learning and quality improvement and asserts that establishing payment policies for such instances may not always be appropriate. The AHA also contends that the NCD must include an appeal process to enable hospitals to petition decisions they believe to have been made inappropriately.

America's Health Insurance Plans (AHIP)

AHIP supports the steps CMS is taking to reduce serious injuries and/or deaths resulting from the surgical errors under analysis in this NCA and CAG-00402N and CAG-00403N. AHIP notes that surgical errors resulting in serious consequences are clearly identifiable and preventable.

American Medical Association (AMA)

The AMA states that the NCD process is not appropriate for addressing concerns regarding surgical errors under analysis in this NCA and CAG-00402N and CAG-00403N, because NCDs establish national policies "on whether Medicare will cover an item or service." They contend that "it would make more sense to develop a clear payment policy outlining the circumstances under which surgery claims would not be payable by Medicare." The AMA also notes "the many nuances surrounding these surgical conditions" and asserts that an appeals process must be included in any policy in order to provide physicians and hospitals a mechanism for petitioning decisions they consider inappropriate.
The AMA also notes CMS' typical NCA process which involves a vigorous evidence review and contends that none of the surgical conditions under analysis in this NCA or CAG-00402N and CAG-00403N present "an issue that would qualify them for development of a NCD." They conclude their comments by urging "CMS to not move forward in the development of new NCDs for these conditions, but rather to explore options for revising Medicare payment policies associated with these three surgical conditions."

Premier Healthcare Alliance

The Premier Healthcare Alliance "agrees with CMS' non-coverage recommendation for surgery on the wrong patient, surgery on the wrong body part, and wrong surgery performed on a patient." Premier requests that with this coverage analysis CMS provide clear definitions for each of the surgical events and their consequences.
Premier asserts that an appeals process should be established because "providers should be able to request a case review when 1) the error that lead to the inappropriate procedure was clearly not the fault of the hospital; 2) an unnecessary or unscheduled procedure is performed, but the correct surgery is also performed and there has been no harm to the patient; 3) extenuating circumstances may explain or necessitate a change in a pre-scheduled procedure; 4) code edits may erroneously identify a case." They also contend that CMS clearly explain "what specifically will not be covered, and whether this means that hospitals are not to bill for these patients or they are to bill, but will not be paid."

VI. Analysis

1. Definition

The National Qualify Forum identified a list of preventable, serious adverse events and developed definitions that would facilitate reporting of such occurrences. We did not locate any other similar nationally accepted method of reporting such events and are therefore adopting the definitions of the events at issue from that list:

> A surgical or other invasive procedure is considered to be the wrong procedure if it is not consistent with the correctly documented informed consent for that patient. It excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. The event is not intended to capture changes in the plan upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation; or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae).

2. Scope

The NQF has defined the scope of procedures included in this event and we agree with that scope. However, as recommended by NQF, we are proposing some changes to avoid confusion of terms within the Medicare program. The term "surgery" has been used regularly throughout the history of the Medicare program in statute, regulation and policy. To define that term as NQF has, has the potential to modify these policies. Thus, we propose, rather than defining "surgery," to define "surgical and other invasive procedures" while still encompassing all procedures included within the NQF definition. We also propose to clarify for Medicare purposes that all CPT codes in the surgery section of the CPT manual are included as well as other invasive procedures such as angioplasty and catheterizations. Thus, we

propose the following scope:

> Surgical and other invasive procedures are defined as operative procedures in which skin or mucous membranes and connective tissue are incised or an instrument is introduced through a natural body orifice. Invasive procedures include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include all codes in the surgery section of the Current Procedural Terminology (CPT) and other invasive procedures such as percutaneous transluminal angioplasty and cardiac catheterization. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include use of instruments such as otoscopes for examinations or very minor procedures such as drawing blood.

3. Coverage
Evidence of harm or lack of evidence of benefit is not necessary to determine that the wrong surgical procedure performed on a Medicare beneficiary does not improve health care outcomes. We have included in the discussion above several prominent healthcare entities that agree with this conclusion. Thus we are proposing that it is not reasonable and necessary to perform the wrong surgical or other invasive procedure on Medicare beneficiaries.

IX. Proposed Decision

The Centers for Medicare and Medicaid Services (CMS) proposes that when a Medicare beneficiary requires a particular surgical or other invasive procedure to treat a particular medical condition and the practitioner erroneously performs a different procedure, Medicare will not pay for that procedure because it is not a reasonable and necessary treatment for the Medicare beneficiary's particular medical condition.

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We are requesting public comments on this proposed determination pursuant to section 1862(1) of the Social Security Act. After considering the public comments, we will make a final determination and issue a final decision memorandum.

[1] http://www.iom.edu/Object.File/Master/4/117/ToErr-8pager.pdf
[2] http://www.qualityforum.org/pdf/reports/sre.pdf
[3] http://www.jointcommission.org/PatientSafety/UniversalProtocol/
[4] http://www.jointcommission.org/NewsRoom/NewsReleases/nr_npgs_gen.htm
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